REMARKS:

Reconsideration of the rejections set forth in the Final Office Action mailed July 17, 2008 and entry of the present amendment is requested because Applicants respectfully submit that the Amendment places the application in condition for allowance or in better form for consideration on appeal.

No claims have been amended. Accordingly, claims 16-25 and 48-74 remain pending with claims 53-62 and 72-74 withdrawn from further consideration.

In the Final Office Action, claims 16-24, 48-52, and 63-71 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,626,899 ("the Houser reference") in view of U.S. Patent No. 6,702,826 ("the Liddicoat reference") and U.S. Publication No. 2005/ 0107871 ("the Realyvasquez reference"), and claim 25 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Houser, Liddicoat, and Realyvasquez references in view of U.S. Patent No. 6,162,233 ("the Williamson, IV reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the Houser reference, clips are disclosed that are intended to be placed over or around a valve. Col. 17, lines 50-51. For example, FIGS. 27A and 27B show a circumferential clip 406 that has opposing ends 408 that are spaced apart from one another such that the clip 406 may be positioned around a valve to provide an inwardly biased spring force to cinch the valve. Col. 16, lines 24-31.

In FIG. 29A-29B, the Houser reference discloses a valve clip 414 having anchoring members 416 on either end of the clip 414. Col. 16, lines 43-45. Similar clips are shown in FIGS.

30A-36B. As shown in FIGS. 42B-42D, 43A and 43B, the ends of the clip are intended to be spaced apart from one another such that ends may be anchored on opposite sides of an existing heart valve. For example, the Houser reference discloses that clip 498a may be compressed in a catheter 490 and positioned over a valve, whereupon the clip 398a may be pushed partially out of the catheter 490 until the farthest anchoring member (or end) of the clip 498a is in contact with and enters edge of valve 402 farthest from the catheter. Col. 20, lines 30-41. As the clip 498a finally exits the catheter, the second anchoring member (or end) is engaged with the edge of the valve 402 closest to the catheter 490. Col. 20, lines 41-43.

FIG. 38 merely shows an example of a clip 454 that has been compressed into a "U" or "V" shape for delivery, i.e., from the shapes shown in FIGS. 29A-36B, and that may be deployed from catheter section 436. Col. 18, lines 51-55. Clearly, once deployed from the catheter section 436, the ends of the clip 454 will move away from one another, i.e., towards the shapes shown in FIGS. 29A-36B, such that the ends may be engaged on opposite sides of a valve.

Turning to the present claims, claim 16 recites a method for attaching a heart valve prosthesis to a tissue annulus using an attachment device comprising a base and a pair of legs extending from the legs, the attachment device being elastically movable from a relaxed state wherein the legs cross one another and a delivery state wherein the legs extend substantially parallel with one another. The method includes loading the attachment device into a tool with the attachment device in the relaxed state; securing the heart valve prosthesis to the tissue annulus using the attachment device while applying a force using the tool to place the attachment device in the delivery state; and releasing the attachment device from the tool such that the attachment device returns towards the relaxed state such that the legs cross one another.

As explained above, the Houser reference clearly does not teach or suggest an attachment device that is loaded into a tool in a relaxed state (wherein the legs cross one another), that is secured to a heart valve prosthesis while applying a force to place the attachment device in a delivery state (wherein the legs extend substantially parallel to one another), and that is released such that the legs again cross one another. In direct contrast, the ends of the Houser clips must move away from one another when deployed from the catheter, which is necessary in order for the ends to engage opposite sides of the valve.

In particular, the Houser clips are not loaded into the catheter in a ***relaxed state wherein the ends of the clips cross one another***. Instead, the Houser clips are ***compressed from a relaxed state*** (the relaxed state being when the ends of the Houser clips are spaced apart from one another) when they are loaded into the catheter. Thus, the Houser clips are loaded and delivered in opposite conditions than the claimed attachment devices.

Neither the Liddicoat staples (or plication bands) 100 nor the Realyvasquez clips 300 may be properly substituted for the Houser clips. First, as explained above, the Houser clips are necessarily intended to have the ends biased away from one another sufficient distance such that the ends may be engaged on opposite sides of a valve to cinch the valve. In contrast, the Realyvasquez clips 300 are intended to be self-closing, i.e., having an open, deformed configuration (shown in FIG. 4A) and a closed, relaxed configuration (shown in FIG. 4C). Also see Realyvasquez paragraph [0043]. Similarly, the ends of the Liddicoat staples are intended to be directed towards one another not away from one another during delivery.

Second, the Realyvasquez clips 300 are sufficiently small such that the ends can be driven through a curved ring 104 of a prosthesis to secure the prosthesis over an existing valve leaflet.

See FIG. 8A. Thus, the clips 300 would be incapable of being engaged with opposite sides of a valve because the clips 300 are orders of magnitude smaller than the Houser clips.

Third, even if the Realyvasquez clips could have their ends engaged with opposite sides of a valve, when the clips were released, the clips would be biased to close, which would twist and close the valve, thereby preventing the valve from operating properly. A person of ordinary skill would recognize that it would not be obvious to substitute the Realyvasquez clips since they would undermine the intended purpose of the Houser clips.

Thus, even if the Realyvasquez clips could be delivered using the Liddicoat tool 131 (which Applicants do not concede given the substantially different configurations of the Liddicoat staples and the Realyvasquez clips), the result would be a device incapable of performing the procedure intended by the Houser reference. Accordingly, for these reasons, claim 16 and its dependent claims are not obvious over the cited references.

In addition, the claims that depend from claim 16 include additional nonobvious features that are neither taught nor suggested by these references. For example, claim 24 recites a heart valve prosthesis that includes a first prosthesis comprising a sewing ring and a second prosthesis comprising a valve structure, and wherein the attachment device is used to attach the first prosthesis within or around the annulus. None of these references discloses, teaches, or suggests such a multiple component heart valve prosthesis. FIG. 8D of the Realyvasquez reference does not teach or suggest such a multiple component prosthesis, but merely shows a one-piece prosthesis 100 being secured along a valve annulus. See paragraphs [0033] and [0057].

Similarly, claim 48 also recites a multiple component prosthesis, which is wholly absent from these references. In particular, the Realyvasquez reference does not teach or suggest securing a first prosthesis to a tissue annulus by inserting a plurality of attachment devices, and ***thereafter***, placing a second prosthesis. Instead, the Realyvasquez reference discloses simultaneously ejecting all of the clips from a delivery apparatus to secure a single prosthesis to the mitral valve “after which the prosthesis delivery apparatus is removed.” Page, 6, paragraph [0057]. The Realyvasquez reference clearly does not disclose, teach, or suggest placing a second prosthesis after this step. Accordingly, claim 48 and its dependent claims are not obvious over the cited references.

Finally, the Williamson, IV reference, identified for disclosing a pledget, merely discloses plastically deformed staples, and therefore fails to provide any additional teaching or suggestion that may be properly combined with the other cited references to render the present claims obvious.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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Dated: September 17, 2008

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